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December 1, 1999

Charles Ganley, MD
Director, Division of Over the Counter Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Docket Number 75N183H

Dear Dr. Ganley:

Further to my letter of December 1, 1999 (copy attached), we would like to add two additional proposed FDA attendees to our request for a meeting:

Maureen Dillon-Parker (Project Manager, Division of Anti-Infective Drug Products)
Albert Sheldon, Ph.D. (Project Manager, Division of Anti-Infective Drug Products)

Again, thank you for your assistance in this matter.

Sincerely,

Annalisa Pizzarello

75N-183H

SUP3

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Charles Ganley, MD
Director, Division of Over the Counter Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville. MD 20857

Re: Docket Number 75N183H

Dear Dr. Ganley:

On behalf of our client International Laboratory Technologies Corp. (ILTC), I am writing to request a meeting regarding the topical antimicrobial drug products monograph (docket number 75N183H), specifically the status of benzalkonium chloride. The purpose of the meeting is to resolve conflicting feedback between Divisions on the data necessary to support safety, efficacy and persistence claims for benzalkonium chloride.

On September 22, 1999, the Division of Anti-Infective Drug Products sent the attached letter to ILTC discussing the data necessary to support safety, efficacy and persistence claims for benzalkonium chloride (concentration 0.10 – 0.13%). The letter refers ILTC to the Division of Over the Counter (OTC) Drug Products to discuss the issue of category 1 designation for this ingredient. On November 30, 1999, in a telephone conversation, the Division of OTC Drug Products indicated that data requirements set forth in this letter might be insufficient. The purpose of the requested meeting, therefore, is to discuss exactly the data necessary from both Divisions' perspectives to support safety, efficacy and persistence claims for this ingredient.

We anticipate the meeting should take approximately one hour and request that the following FDA attendees be present:

Gary Chikami, MD (Director, Division of Anti-Infective Drug Products)
Charles Ganley, MD (Director, Division of OTC Drug Products)
Linda Katz, MD, MPH (Deputy Director, Division of OTC Drug Products)
Daiva Shetty, MD (Medical Officer, Division of OTC Drug Products)
Kerry Rothschild (Project Manager)

Debbie Lumpkins (Interdisciplinary Scientist)

From ILTC, David Moll (President and CEO) will attend, and from Arnold & Porter William Vodra and I will attend.

We will provide documentation of the studies performed by ILTC on benzalkonium chloride as soon as the meeting is scheduled.

Thank you for your assistance in this matter.

Sincerely,

Annalisa Pizzarello

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

International Laboratory Technology Corp.
Attention: David Moll
President and CEO
3389 Sheridan Street
Suite 149
Hollywood, Florida 33021

SEP 22 1999

Dear Mr. Moll:

Please refer to your correspondence dated August 18, 1999, requesting confirmation of the *in vitro* and *in vivo* test requirements for an antiseptic handwash product with the active ingredient benzalkonium chloride in a concentration between 0.10 and 0.13%.

As discussed with Dr. Albert Sheldon and Mr. David Bostwick of this Division and Ms. Debbie Lumpkins of the Division of Over-the-Counter Drug Products, the following tests as outlined in. your correspondence will provide the data necessary to support safety, efficacy and persistence claims, as well as support the inclusion of the ingredient Benzalkonium chloride for use in the Tentative Final Monograph for Health-Care Antiseptic Drug Products dated June 17, 1994.

In vitro Tests

1. A time kill study conducted per the Tentative Final Monograph (TFM) for Health-Care Antiseptic Drug Products dated June 17, 1994.

2. An MIC study using 50 strains of each organism listed in the monograph against the test product, 10 strains of each with the vehicle and a positive control (Hibiclens).

In vivo Tests

1. Conduct a Healthcare antiseptic handwash study as outlined in the TFM. This study should include a total of 60 subjects, 30 treated with the test product and 30 treated with a reference product. If it becomes necessary to market this product through the NDA process, a 3-arm study would be required. This would require the addition of a vehicle control arm.

2. A cylinder Sampling Test and an Agar Patch Test to demonstrate persistence.

Please be reminded that the active ingredient, benzylkonium chloride is addressed in the TFM as one of the ingredients that can be marketed as long as the product meets the requirements for strength and passes the *in vitro*, time-kill kinetic, and clinical simulation studies described there in.

If this product is to be submitted as a New Drug Application, human irritation and sensitization testing will also be necessary.

The Division of Over-the-Counter Drug Products should be contacted regarding the issue of Category 1 designation.

If you have any questions, contact Ms. Maureen Dillon-Parker, Project Manager, at (301) 827-2125.

Sincerely,

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research